

FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)				ATTY DOCKET NO. 5045-56103USCIP		APPLICATION NO. 06/860,577	
				APPLICANT <i>Eugenio Cafali, et al.</i>			
				FILING DATE 31 October 1997		GROUP 1615	

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	

FOREIGN PATENT DOCUMENTS							
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT		

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
DOCUMENTS SUBMITTED UNDER MPEP § 724							
<div style="font-size: 2em; margin: 0;"> </div>	<div style="float: right; text-align: right;"> RECEIVED JAN 04 2005 OFFICE OF PETITIONS </div> <p>Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order</p> <p>Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] - Subject to Protective Order</p> <p>Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) - Subject to Protective Order</p> <p>Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order</p> <p>Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] - Subject to Protective Order</p> <p>Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order</p> <p>Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order</p> <p>Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004) - Subject to Protective Order</p>						
EXAMINER	<div style="display: flex; justify-content: space-between;"> <i>L. Channarayana</i> DATE CONSIDERED <i>12/29/05</i> </div>						

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

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 03/680,677
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		APPLICANT Eugenio Cafal, et al.	
		FILING DATE 31 October 1997 JAN 04 2005 OFFICE OF PETITIONS	GROUP 1615
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)			
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
DOCUMENTS SUBMITTED UNDER MPEP § 724			
		Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) - Subject to Protective Order	
		Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) - Subject to Protective Order	
		Rebuttal Expert Report of James W. McGinly, Ph.D. (April 2, 2004) - Subject to Protective Order	
		Supplemental Rebuttal Expert Report of James W. McGinly, Ph.D. (August 18, 2004) - Subject to Protective Order	
		Rebuttal Expert Report of James W. McGinly, Ph.D. Regarding The '967 Patent (September 30, 2004) - Subject to Protective Order	
		Expert Report of Mark E. McGovern, M.D. (February 6, 2004) - Subject to Protective Order	
		Expert Report of Mark E. McGovern, M.D. (August 20, 2004) - Subject to Protective Order	
		Expert Report of Frank M. Sacks, M.D. (April 2, 2004) - Subject to Protective Order	
		Expert Report of Frank M. Sacks, M.D. (August 20, 2004) - Subject to Protective Order	
		Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) - Subject to Protective Order		

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FORM PTO 1448 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)	ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 02/060,577
	APPLICANT <i>Eugenio Cefali, et al.</i>	
	FILING DATE 31 October 1997	GROUP 1815
OTHER DOCUMENT(S) (including Author, Title, Date, Pertinent Pages, Etc.)		
DOCUMENTS SUBMITTED UNDER MPEP § 724		
	Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order	
	Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order	
EXAMINER <i>L. Channarayana</i>	DATE CONSIDERED <i>12/29/05</i>	

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FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/680,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		APPLICANT Eugenio Cafati, et al.	
		<div style="text-align: center;">RECEIVED</div> <div style="display: flex; justify-content: space-between;"> JAN 04 2005 GROUP 1615 </div>	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997 OFFICE OF PETITIONS	
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
	Carl J. Lavie, et al., <i>Marked Benefit with Sustained-Release Niacin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease</i>, Am. J. Cardiol. 1992;69:1083-1085		
	Excerpts from the 1993, 2000 and 2002 editions of the Physician's Desk Reference 1993 edition (pp. 434, 611, 856, 1189, 1919, 1920, 2491 and 2492) 2000 edition (pp. 1519-1523) 2002 edition (pp. 1846-1850)		
	<i>Niacin: Double-edged Sword for Lowering Cholesterol</i>, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6		
	Larsen, ML and Illingworth, DR, <i>Drug Treatment of Dyslipoproteinemia</i>, Med Clin N Am., 78:225-245 (1994)		
	Lavie, Letter to Editor, JAMA 1994; 272:513-515		
	Keenan, Letter to Editor, JAMA 1994; 272:513-515		
	Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515		
	Thomas N. Tozer, <i>Clinical Pharmacokinetics Concepts and Applications</i> (3d ed. 1995) at Chapter 9, p. 120		
	Excerpts from the 1995 United States Pharmacopela (pp. iii-vi, 1080-1082, 1793-1799, 1940-1944)		
	Morgan & Capuzzi Abstract, <i>Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin</i>, Clinical Pharmacology & Therapeutics (February 1996)		
	Morgan & Capuzzi Article, <i>Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial</i>, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996)		
EXAMINER	L. Channarayana		DATE CONSIDERED 12/29/05

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FORM PTO 1448 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/980,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		APPLICANT Eugenio Cofa, et al.	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		<div style="text-align: center;"> RECEIVED JAN 04 2005 </div>	
		FILED DATE 31 October 1997	GROUP 1615
OTHER DOCUMENT(S) (including Author, Title, Date, Periodical, etc.)			
B		Capuzzi DM, et al., Efficacy and Safety of An Extended-Release Niacin (Niaspan): A Long-Term Study, Am J Cardiol. 1998;82:74U-81U	
		Guyton JR, Advances in Dyslipidemia: Discussion Session II, Am J Cardiol, 1998: 82(12A): 85U-86U	
		Knopp RH, et al., Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia, Metabolism 47:1097-1104 (1998)	
		American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 21:179-182, 1998	
		Elam MB, et al., Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease, JAMA: 2000; 284:1263-1270	
		Kesala R, et al., Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP), Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000)	
		2001 NCEP Report at VI-11, Table VI.2-3	
		Wang, W. et al., Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001)	
		Smith SC, et al., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update. AHA/ACC Scientific Statement, 1577-79	
V		Tavintharan S and Kashyap M, The Benefits of Niacin in Atherosclerosis, Curr Athero. Reports 2001; 3:74-82	
EXAMINER	L. Channarayana		DATE CONSIDERED 12/29/02

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OFFICE OF PETITIONS			
OTHER DOCUMENT(S) (Including Author, Title, Date, Portion Pages, Etc.)			
✍		Meadows M., <i>Serious Liver Injury: Leading Reason for Drug Removals, Restrictions</i>, FDA Consumer Magazine, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html	
		Grundy SM, et al., <i>Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes</i>. Arch Intern Med. 2002; 162: 1568-1576	
		American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i>, Diabetes Care 25:S74-S77, 2002	
		Pan J, et al., <i>Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism 4:255-261 (2002)</i>	
		Pan J, et al., <i>Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes</i>, Metabolism 51:1120-1127 (2002)	
		Meyers CD, et al., <i>Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia</i>, Ann Intern Med. 2003; 139:996-1002	
		CDER Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations</i> (March 2003)	
✓		American Diabetes Association: <i>Dyslipidemia Management in Adults with Diabetes</i>, Diabetes Care 27:S68-S71, 2004	
EXAMINER L. Channarayana		DATE CONSIDERED 12/29/05	

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